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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/585,925 | 06/02/2000 | Paul Rafferty | 2079.1024008 | 6299 |

7590 03/27/2002
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Boston, MA 02109

EXAMINER

LIU, HONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 03/27/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary

Application No.

09/585,925

Applicant(s)

Rafferty et al.

Examiner

Hong Liu

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 4, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-26, 37, and 38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 is/are rejected.
- 7) ☒ Claim(s) 37 and 38 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claims 16-26 are pending in this application.

This action is in response to the applicants' amendment and reply filed on February 4, 2002.

Response to Arguments

Applicants' arguments filed on September 24, 2001 have been fully considered but they are not persuasive. Rejection to Claims under 35 U.S.C. 112, first paragraph and second paragraph is maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 16-26 and 36 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. Although applicants' arguments about Q capable of being N is persuasive, the claims are still not commensurate in scope as to the diversity of Markush groups, aromatic groups, heteroaromatic and heterocyclic groups which all permit further substitution on the purine ring. The instant case is similar to *In re Lund*, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. Applicants urge that the compounds embraced herein are active as receptor tyrosine kinase antagonists, and thus all of the functional

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moieties and heterocyclic/aromatic groups which are embraced by these claims have the activity of inhibiting receptor tyrosine kinases. However, no reasons and evidence have been provided to support applicants' position. Applicants have not provided adequate information that the instant compounds **as an entire class** have the required activities needed to practice the invention, and therefore, there is no reasonable basis for assuming that the variety of substituents embraced by the claims will all share the same physiological properties. See MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Note also the quote taken from *Surrey*, previously cited, "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" these compounds either." Also note the quote taken from *In re Cavallito* 127 USPQ 202 which was cited in *Surrey*, previously cited, at page 730; "...where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful...An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." Note Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouche*, 169 USPQ 429. Furthermore, applicants rely on the working examples in the specification, but as mentioned before, these examples are limited to a homogenous group of compounds. While every claimed

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embodiment need not be shown to possess the requisite activity needed to practice the invention, there must be a showing that is **representative** of the claimed scope. Applicants provide no sound reasoning why one skilled in the art should or would accept the working examples drawn to compounds wherein R is pyrrole, indole, pyrrolo[2,3-b]pyridine as being representative. Note In re Armbruster, 185 USPQ 152, wherein it was stated that a specification which “describes the invention as broadly as it is claimed...does not necessarily also “enable” one skilled in the art to make or use the claimed.

Claims 16-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A large number of provisos have been included in the claim (see amended claim 1). The proviso lacks description. Even negative limitations require a description. The MPEP at 2173.05(I) Negative Limitation states “Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff’d mem.*, 738 F. 2d 453 (Fed. Cir. 1984)” and further, “Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.” In the instant case, the new concept that has been introduced by the proviso is the specific relationships between R, R14, and R15. This specific relationship of connectivity was previously

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not disclosed. This notion that the definition of one variable depends on the definitions of other variables is new. The definition of a variable is no longer independent.

Rejections 1) and 4) to claims 16-26 under 35 U.S.C. 112, second paragraph, is maintained for reasons already made of record. As stated, the term "heteroaryl" does not specify the ring systems, heteroatoms, etc. See *In re Wiggins* 179 USPQ 421 for certain terminology regarding heterocyclic ring systems. Applicants argue that these terms are defined in the specification and thus are definite and enabled when they are read in light of the specification. However, reading a claim in light of the specification is quite different from reading limitations of the specification into the claim. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541. These claims themselves do not carry the limitation as specified in the specification. When the claims having these phrases are given the broadest interpretation, it is still open-ended in terms of the array of heteroatoms, size of the rings, as well as nature of atoms as ring members.

In claim 16, R2 is vague and indefinite. A substituent can be anything.

In claims 20 and 21, R can be tetrahydrofuran which is non-aromatic, which contradicts the definition of R2.

Claim Rejections - 35 USC § 102

In view of the current provisos in the claim, the 102 is withdrawn.

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Claim Rejections - 35 USC § 103

the rejection to claims under 35 U.S.C. 103(a) is hereby withdrawn for the same reason given in the 102 rejection.

Claim Objections

Claims 37 and 38 are newly added claims which might contain new matter. Applicants are required to point out the support of the claims in the specification to avoid new matter rejection.

Conclusion

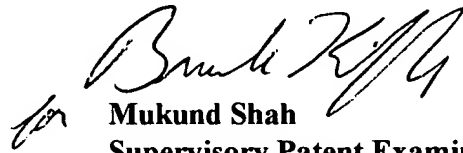
1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

hl
March 23, 2002


Mukund Shah
Supervisory Patent Examiner
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